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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,662	12/22/2000	Lechoslaw Turski	102286-123	1433

23483 7590 03/06/2003

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EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/746,662		TURSKI ET AL.	
	Examiner		Art Unit	
	Ruixiang Li		1646	

-- The MAILING DATE of this communication appears n th cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/30/2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-28 and 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25, 29, 30, and 38 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 13 on December 30, 2002 has been entered in full. Claims 1-14 and 18-20 have been canceled. Claims 21-38 have been added. Claims 21-38 are pending.

On reviewing the restriction requirement set forth in Paper No. 7, the Examiner realized that claims 10 and 12, which are drawn to non-elected species (AMPA receptor channel blockers), were erroneously examined in previous office action (Paper No. 10, mailed on July 29, 2002). These claims correspond to newly added claims 27 and 28 in the amendment (Paper No. 13). Claims 26 and 31-37 are also drawn to non-elected species (due to cancellation elected species, amino- or desamino-2,3-benzodiazepine). Therefore, only claims 21-25, 29, 30, and 38 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Objections and/or Rejections

All the rejection and objection of claims, as set forth in the previous Office Action (Paper No. 10, July 29, 2002), has been withdrawn in view of applicants' cancellation of all the claims.

III. Information Disclosure Statement

The Information Disclosure Statement submitted on December 30, 2002 in Paper No. 11 is acknowledged. The references listed in Form PTO-1449 have been fully considered. The 1.17(p) fee (\$180.000) has been charged.

IV. Claim Rejections Under 35 U. S. C. § 103

(i) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(ii) Claims 21, 22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shishikura et al. (U.S. Patent No.6,133,258, Published on October 17, 2000; 102(e) date: May 13, 1998) in view of Csuzdi et al. (WO 97/28163, August 7, 1997).

Shishikura et al. teach a method of treating multiple sclerosis, which is a demyelinating disorder, with an AMPA receptor antagonist (pyridothiazine derivatives; see, e.g., 3rd to 5th paragraphs of column 2; claims 7-9).

Shishikura et al. fail to teach a method of treating a demyelinating disorder with the inhibitor of AMPA receptor, amino- or desamino-2,3-benzodiazepine.

Csuzdi et al. teach condensed 2,3-benzodiazepine derivatives, including amino- or desamino-2,3-benzodiazepine, a pharmaceutical composition comprising

the compounds, and their use as AMPA receptor non-competitive inhibitors for treating neurological disorders (See, e.g., Abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat multiple sclerosis by administering an AMPA receptor inhibitor, e.g., amino- or desamino-2,3-benzodiazepine taught by Csuzdi et al. with a reasonable expectation of success. One would have been motivated to do so because Shishikura et al. teach that an AMPA receptor antagonist is useful for treating multiple sclerosis, a demyelinating disorder.

(iii) Claims 23, 29, 30, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shishikura et al. (U.S. Patent No.6,133,258) in view of Csuzdi et al. (WO 97/28163) as applied to claims 21, 22, 24, and 25 above, and further in view of Prineas et al. (*IDS*, Demyelinating Diseases, in Greenfield's Neuropathology, Chapter 13, pages 813-896, 1997).

Shishikura et al. teach a method of treating multiple sclerosis, which is a demyelinating disorder, with an AMPA receptor antagonist.

Csuzdi et al. teach condensed 2,3-benzodiazepine derivatives, including amino- or desamino-2,3-benzodiazepine, a pharmaceutical composition comprising the compounds, and their use as AMPA receptor non-competitive inhibitors for treating neurological disorders (See, e.g., Abstract).

Both Shishikura et al. and Csuzdi et al. fail to teach (i) a method of treating a demyelinating disorder by administering a pharmaceutical composition comprising an

inhibitor of AMPA receptor in combination with a second agent, e.g., interferon; and (ii) the specific secondary demyelinating disorders listed in claim 23.

Prineas et al. teach (i) that interferon- β curtails immune activation by counteracting some of the proinflammatory actions of interferon- γ and reduces the rate of clinical relapses of multiple sclerosis (3rd paragraph, left column of page 857); and (ii) the general pathological features of demyelinating disorders.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made (i) to treat multiple sclerosis by administering a pharmaceutical composition comprising an AMPA receptor antagonist taught by Shishikura et al. in combination with interferon- β (either simultaneously or separately) or (ii) to treat the specific secondary demyelinating disorders listed in claim 23 with a reasonable expectation of success. One would have been motivated to do so because (i) both an AMPA receptor antagonist and interferon- β are beneficial for the treatment of multiple sclerosis and an artisan would reasonably expect the combination of the two compounds to be beneficial for the same purpose, i.e., treating multiple sclerosis; and (ii) Shishikura et al. teach that an AMPA receptor antagonist is beneficial for treating a demyelinating disorder (multiple sclerosis) and one skilled in the art would reasonably expect the treatment with an AMPA receptor antagonist to be beneficial for treating a different type of demyelinating disorder, such as a secondary demyelinating disorder listed in claim 23.

V. Conclusion

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
March 4, 2003

Elyabek C. Kemme

STAMPED SIGNATURE